



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/924,112 | 08/07/2001 | Bernhard Dietzschold | DIE01-NP002 | 9826 |

7590 01/28/2004

Daniel A Monaco Esq.
Drinker Biddle & Reath LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996

| |
|----------|
| EXAMINER |
|----------|

FOLEY, SHANON A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1648 | |

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,112

Applicant(s)

DIETZSCHOLD ET AL.

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) received
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I in the paper received October 18, 2003 is acknowledged. However, upon reconsideration, group II is rejoined with group I. The following restriction has been reformulated to reflect this change:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to an expression vector comprising a non-segmented RNA virus expressing a cDNA encoding an immunoglobulin heavy chain and/or an immunoglobulin light chain, classified in class 435, subclass 320.1 and class 536, subclass 23.53.
- II. Claims 4 and 5, drawn to a method of expressing a functional immunoglobulin, classified in class 435, subclasses 70.21 and 326.
- III. Claims 6 and 8, drawn to a method of treating or preventing a condition by administering an antibody, classified in class 424, subclass 130.1.
- IV. Claims 7 and 9, drawn to a method of treating or preventing a condition by administering a purified viral vector and a vector comprising a recombinant non-segmented, negative-stranded RNA virus vector expressing an antibody, classified in class 424, subclasses 202.1, 199.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

Art Unit: 1648

made by another and materially different process (MPEP § 806.05(f)). In the instant case, the antibody can be made by a materially different process, such as expression in a hybridoma cell line.

Inventions I and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of treating and preventing can be practiced by administering an antibody or administering a purified viral vector and a vector comprising a recombinant non-segmented, negative-stranded RNA virus vector expressing an antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper. In addition, issues that may arise during examination of one group may not arise in the examination of another group.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

According to applicant's election without traverse of group I, claims 4-9 are withdrawn from consideration due to a non-elected invention and claims 1-3 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mebatsion et al. (reference AF from the IDS submitted December 31, 2002) and Owens et al. (reference AO from the IDS submitted May 7, 2002).

The claims are drawn to an expression vector comprising a recombinant non-segmented, negative-stranded RNA virus expressing a cDNA encoding an immunoglobulin light chain and/or an immunoglobulin heavy chain.

Owens et al. provide a minireview of conventional recombinant techniques for engineering monoclonal antibodies. On pages 157-158, Owens et al. describe vectors separately expressing an immunoglobulin light chain and an immunoglobulin heavy chain and co-amplifying immunoglobulin heavy and light chains in the same vector. Owens et al. do not teach using a non-segmented, negative-stranded RNA virus to express the antibody chains.

However, Mebatsion et al. teach stable and high expression of a heterologous cDNA inserted into a rabies virus vector, see "Expression of CAT and Stability of the Foreign Gene" on page 7312.

One of ordinary skill in the art at the time the invention was made would have been motivated to express an immunoglobulin heavy chain and/or an immunoglobulin light chain in a non-segmented, negative-stranded RNA virus because its genome facilitates the insertion of

Art Unit: 1648

heterologous cDNAs, provides highly stable expression of the insert and eliminates the possibility of nuclear splicing due to cytoplasmic amplification, see the introduction and discussion sections of Mebatsion et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for expressing immunoglobulin light and/or heavy chains in a non-segmented, negative-stranded RNA virus vector because light and heavy chains are conventionally expressed in vectors and non-segmented, negative-stranded RNA viruses easily accept and stably express foreign gene insertions. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley